APIC comments on: Draft FDA Guidance for Industry: Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations".

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Guidance for Industry: Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations

Introduction.

CEFIC is the European organization of the chemical industry representing national federations, companies and more than 100 affiliated associations and sector groups, located in Europe. All together CEFIC represents directly or indirectly more than 29,000 large-, medium- and small chemical companies in Europe which employ about 1.7 million people and account for nearly a third of the world chemical production.
APIC is one of CEFIC sector groups, comprising European producers of active pharmaceutical ingredients (APIs) and intermediates. This product range implies that CEFIC/APIC is a major stakeholder regarding new pharmaceutical Regulations and Guidelines, in particular for those that affect APIs and intermediates.
We, therefore, take the opportunity for submitting our members' comments on the above-mentioned Draft Guidance.
We have limited our comments hereunder to "General Comments" because of the character of the comments.

General Comments.

CEFIC/APIC very much support this document because it is very helpful to modernize and to harmonize quality systems in the pharmaceutical industry.
We are a bit disappointed by the fact that the scope of the document is limited to drug products (finished pharmaceuticals). In our opinion the scope of this document should also include specific reference to the manufacture of Active Pharmaceutical Ingredients (API). The approach of Quality systems is as much applicable for API manufacturers as for drug product manufacturers.

Furthermore in the document reference can then be made to the GMP requirements for APIs (ICH Q7a).

We trust that you will take this matter into consideration and look forward to reading from you very soon.

Yours sincerely,

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